

SJ-EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION MDL No. 2804  
OPIATE LITIGATION

Case No. 17-md-2804  
Judge Dan Aaron

This Document Relates To: Polster

The County of Lake, Ohio v.  
Purdue Pharma L.P., et al.  
Case No. 18-op-45032

The County of Trumbull, Ohio v.  
Purdue Pharma L.P., et al.,  
Case No. 18-op-45079

Track 3 Cases

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Remote videotaped deposition of
LEWIS COLOSIMO

March 15, 2021
9:31 a.m.

Renee L. Pellegrino, RPR, CLR
(Appearing Remotely)

1 office as a diversion investigator, and most
2 recently, approximately two weeks ago, I have
3 been the group supervisor, group supervisor for
4 the diversion group in the Pittsburgh district
5 office.

6 Q. And as a group supervisor, do you --
7 I assume you supervise other diversion
8 investigators for the DEA?

9 A. Correct.

10 Q. And would it be fair to say that one
11 of the DEA's missions is to try to prevent the
12 use and sale of illegal drugs?

13 A. I can explain as a diversion
14 investigator one of our duties involves the
15 prevention of the diversion of pharmaceutical
16 controlled substances.

17 Q. Okay. And I mean prescription drugs
18 essentially. Is that what you're talking about
19 with respect --

20 A. Prescription drugs as well as
21 scheduled listed chemicals, such as
22 pseudoephedrine and ephedrine.

23 Q. But does the DEA also try to prevent
24 the use and sale of illegal drugs, like, for
25 example, heroin and cocaine?

1 Q. But generally a doctor needs to
2 obtain -- in order to prescribe medication as
3 part of their practice, they need to obtain a
4 DEA license to do that?

5 A. Generally, yes.

6 Q. And the same would be true with
7 respect to a pharmacy; that if a pharmacy is
8 going to be dispensing controlled substances,
9 they would need to obtain a DEA license to do
10 that?

11 A. Correct.

12 Q. And I think you mentioned hospitals.
13 Hospitals would likewise have to have a license
14 to prescribe controlled substances?

15 A. Yes, or administer or dispense to a
16 patient.

17 Q. And with respect to distributors who
18 distribute drugs to doctors and pharmacies for
19 ultimate dispensing to the public, do they have
20 to have a DEA license if they're distributing
21 controlled substances?

22 A. They do.

23 Q. Now, in order to or as part of DEA's
24 efforts to enforce these controlled substance
25 regulations, does the DEA require someone who's

1 applying for a license essentially, like a
2 distributor -- let's take a distributor, for
3 example. If a distributor is applying for a
4 license, do you do a -- sort of a
5 pre-authorization inspection of their facilities
6 and everything to make sure that they're in
7 compliance or going to be in compliance with all
8 the applicable regulations?

9 A. Yes, we do an investigation to
10 determine that they're eligible to engage in
11 that activity.

12 Q. What do you call that? Is that a
13 pre-registration inspection or pre-authorization
14 inspection? I'm not sure. What terminology do
15 you use?

16 A. I personally and others that I work
17 with refer to that as a pre-registrant
18 investigation.

19 Q. And are those inspections important
20 in terms of trying to make sure that anybody who
21 has -- any distributor who has a DEA license is
22 going to be able to comply with all of the
23 controlled substance regulations?

24 MS. CARROLL: Objection. Form.

25 The witness may answer.

1 A. Could you repeat the question? I'm
2 sorry.

3 Q. Yes.

4 Well, is that pre-registrant
5 inspection an important tool that the DEA uses
6 to make sure that somebody who is going to be
7 distributing controlled substances with a DEA
8 license is going to be able to comply with the
9 applicable DEA controlled substances
10 regulations?

11 A. That investigation is certainly
12 part of what I'm tasked or a diversion
13 investigator might be tasked to do, certainly.

14 Q. Now, we didn't talk about this
15 earlier when you were mentioning that, you know,
16 you've been with the DEA for many years. Have
17 you always been geographically in western
18 Pennsylvania as a DEA agent?

19 A. A DEA investigator would be the
20 proper -- a diversion investigator. I have
21 worked I indicated exclusively in the
22 Pittsburgh district office, covering western
23 Pennsylvania is our area of responsibility.

24 Q. How many pre-registrant inspections
25 have you either performed or at least been

1 involved with since you've been with the DEA,
2 just roughly, just a general idea?

3 A. That would be a difficult question
4 to answer. These are investigations that I've
5 done throughout the course of my career, but it
6 would be difficult to even give a rough
7 estimate of how many of these I've done.

8 Q. Well, maybe how about in the last
9 year how many have you done, if you can recall?

10 A. You know what, I don't know. Part
11 of this -- part of these investigations involve
12 a gamut of different types of activities. I
13 think any of those probably would have been for
14 a researcher that was using controlled
15 substances for research purposes.

16 Q. Do you have a sense of how many
17 distributors of controlled substances are in
18 your geographical area, the western Pennsylvania
19 area?

20 A. I don't know the exact number. I'm
21 not sure how many that would be. I can't
22 answer that accurately.

23 Q. You're familiar with Giant Eagle?

24 A. Yes.

25 Q. And Giant Eagle is a distributor of

1 controlled substances?

2 A. Yes.

3 Q. And they distribute the controlled
4 substances to their own pharmacies in their
5 grocery stores?

6 MR. MOUGEY: Objection.

7 A. That's my understanding.

8 Q. Meaning that they don't distribute
9 to like other company -- pharmacies owned by
10 other companies, correct?

11 A. To my knowledge, that's correct.
12 I -- I can't say definitively if they don't,
13 but my understanding is that they sell
14 exclusively to Giant Eagle pharmacies.

15 Q. Are you familiar with McKesson as a
16 drug distributor?

17 A. McKesson drug, yes.

18 Q. Okay. And they have a distribution
19 facility in New Castle; is that correct?

20 A. Correct.

21 Q. Have you inspected their facility in
22 New Castle?

23 A. I have.

24 MS. CARROLL: Objection. This is
25 an objection as to the scope of the testimony.

1 Q. Mr. Colosimo, has the DEA trained
2 you in terms of trying to make sure you
3 understand all the controlled substances
4 regulations and what they require? Have you
5 received any training from the DEA with respect
6 to that?

7 A. I have received training, yes.

8 Q. And what has that training involved?

9 A. Well, initially upon hire by DEA, I
10 received training at DEA's academy. It was
11 considered a basic diversion investigator
12 class, and periodically, throughout the course
13 of my career, I received training from DEA.

14 Q. Now, after a registrant obtains a
15 DEA license with respect to controlled
16 substances, does that licensing or registrant
17 have to undergo periodic inspections to make
18 sure that they have remained in compliance with
19 the applicable DEA controlled substance
20 regulations?

21 A. Yes. These registrants, such as a
22 distributor, would be subject to inspections.

23 Q. Are they called cyclic
24 investigations, or inspections? I'm sorry.

25 A. That's -- that's one phrase that

1 has been used.

2 Q. When you do a pre-registrant
3 inspection, what -- can you tell us what that
4 entails, what that involves, what you look at,
5 and how you conduct the inspection?

6 MS. CARROLL: Objection. Form.
7 The witness may answer.

8 A. Pardon me?

9 Q. Yes. I'm just asking you, can you
10 tell the jury what a pre-registrant inspection
11 involves, what do you do as part of that
12 inspection?

13 MS. CARROLL: Objection. Form.
14 The witness may answer.

15 A. Part of that pre-registrant
16 investigation would involve a review of the
17 applicant's security procedures they have in
18 place, any history they may have with the
19 handling of controlled substances or listed
20 chemicals, any proposed recordkeeping that they
21 have in place. It would require an on-site
22 inspection of the facility and a meeting with
23 certain personnel, you know, that would be
24 employed by the applicant that would be able to
25 address questions regarding security,

1 recordkeeping, personnel issues. That would be
2 a general criteria that we consider.

3 Q. And how many diversion investigators
4 typically are involved in a pre-registrant
5 inspection?

6 A. I mean, I could only speak to
7 myself. I don't know how many typically are
8 involved, but from one to several.

9 Q. And does -- is a group supervisor
10 typically involved or does a group supervisor
11 have to approve the inspection?

12 MS. CARROLL: Objection. Form.
13 The witness may answer.

14 A. A group supervisor may or may not
15 be involved. That would be at their
16 discretion.

17 Q. And if you find that there's
18 anything that is not in compliance with the DEA
19 regulations during a pre-registrant inspection,
20 what do you do about that?

21 A. What I have done would be to bring
22 that to the attention of the group supervisor
23 for discussion.

24 Q. Okay. And then what -- with respect
25 to the registrant or proposed registrant, do you

1 bring that to the registrant's attention, that
2 there's an issue regarding compliance?

3 A. Well, that would be something that
4 would need to be addressed with the applicant.

5 Q. And do you withhold the grant of the
6 license until the proposed registrant has, you
7 know, remedied the non-compliance?

8 A. The decision for that would be the
9 group supervisor's decision whether to approve
10 or to deny the application.

11 Q. Just if you recall -- I know you've
12 been with the DEA for many years, but has that
13 situation ever arisen where a registrant's
14 application was denied that you were involved
15 with?

16 A. That has happened on occasion.

17 Q. Can you identify the -- what you
18 view as sort of the principal sources of
19 diversion that you're on the watch for when
20 you're inspecting registrants?

21 A. Could you be more specific with
22 that question, please?

23 Q. Well, maybe I'll just ask it
24 slightly differently. What, in your view as a
25 DEA inspector, diversion inspector, do you

1 Q. Do you know a Rick Shaheen?

2 A. Yes.

3 Q. How do you know Mr. Shaheen?

4 A. I know of Mr. Shaheen through his
5 employment with the Pennsylvania Office of
6 Attorney General as well as his position with
7 Giant Eagle.

8 Q. How did you come to know him when he
9 was with the Pennsylvania Attorney General's
10 Office? Did you work on some investigations
11 together?

12 A. Yes. My understanding is that
13 Mr. Shaheen was an agent with the Medicaid
14 fraud unit with the Office of Attorney General,
15 and then later was employed there as a
16 supervisor, supervising other agents within
17 that unit.

18 Q. Okay. And did you actually work on
19 any drug investigation, you know, drug
20 investigations with Mr. Shaheen when he was with
21 the Office of Attorney General?

22 A. Yes.

23 Q. And then you mentioned his position
24 with Giant Eagle. Did he obtain that position
25 around 2013? Does that sound right?

1 MS. CARROLL: Objection. Form.

2 The witness may answer.

3 A. I don't know when he accepted that
4 position. I would be guessing.

5 Q. Well, when do you first recall
6 working with him when he was in his new position
7 with Giant Eagle?

8 A. It's been -- I know he's been
9 employed there for several years. I can't
10 recall the first time that I worked with him.

11 Q. And do you know what his position is
12 with Giant Eagle?

13 A. My understanding, pharmacy
14 investigator.

15 Q. Would you agree that one of
16 Mr. Shaheen's jobs is to help prevent drug
17 diversion?

18 A. That's my understanding of part of
19 what his role is with Giant Eagle.

20 Q. So part of his job is to try to make
21 sure that no drug diversion occurs with respect
22 to Giant Eagle's distribution or pharmacy
23 facilities, right?

24 MS. CARROLL: Objection. Form.

25 The witness may answer.

1 A. I don't know all of his
2 responsibilities of -- what Giant Eagle has
3 tasked him to do.

4 Q. In your dealings with Mr. Shaheen
5 have you found him to be a conscientious and
6 competent with respect to trying to prevent drug
7 diversion?

8 A. I can't -- could you be more
9 specific with that question, please?

10 Q. Well, let me -- have you worked with
11 Mr. Shaheen in trying to catch any bad guys with
12 respect to drug diversion?

13 MS. CARROLL: Objection. Form.

14 Q. You know, any investigations where
15 maybe, you know, Mr. Shaheen has called you up
16 and said, I think we have a bad script here or
17 something like that, you know, has given you
18 information about a potential issue?

19 MS. CARROLL: Objection.

20 A. Yes. I've worked many times with
21 Mr. Shaheen on those types of scenarios,
22 correct.

23 Q. And with respect to your dealings
24 with Mr. Shaheen when you guys are both working
25 together to try to prevent diversion, have you

1 found him to be, you know, conscientious, hard
2 working and devoted toward preventing diversion?

3 MS. CARROLL: Objection. Form.

4 The witness may answer.

5 A. From my perspective, Mr. Shaheen
6 has provided cooperation with -- with DEA, with
7 myself personally on the types of diversion
8 investigations that I have -- that I have
9 worked on. He has offered cooperation.

10 Q. Would it be fair to say that he's
11 always cooperated with you?

12 A. I can't recall of any specific
13 cases where he did not cooperate with me at
14 least outwardly, if that's -- that could be a
15 way to put it. I don't know of any cases where
16 he was not cooperative with me.

17 Q. And would it be fair to say that
18 sometimes he calls you with sort of some
19 information or a tip with respect to an issue
20 and sometimes you call him asking him for some
21 help with respect to an investigation, the
22 relationship goes both ways?

23 MS. CARROLL: Objection to form.

24 The witness may answer.

25 A. I have asked for his cooperation

1 specifically with regard to activity that has
2 occurred at Giant Eagle pharmacies and
3 Mr. Shaheen has provided information, concerns
4 or suspicions regarding diversion to me.

5 Q. Has he sometimes just called you out
6 of the blue with some information about a
7 potential problem or issue relating to drug
8 diversion?

9 A. I don't know that I would say out
10 of the blue, but he has called me with
11 information.

12 Q. And information that you did not
13 previously have?

14 A. I would say that on occasion that's
15 correct.

16 Q. Has Mr. Shaheen always been
17 responsive to any requests you've made of him?

18 A. My understanding is he has been
19 responsive to requests for information for --
20 yes, for information, correct.

21 Q. Now, does the DEA have a diversion
22 investigator's manual?

23 A. Yes.

24 Q. Are you familiar with that manual?

25 A. I'm somewhat familiar with that.

1 Do you see that?

2 A. Yes.

3 Q. So, again, that's really one of the
4 things that your -- one of the overarching goals
5 is to make sure that a pre-registrant is going
6 to be able to -- is going to have effective
7 controls against diversion, correct?

8 A. That's something that we consider
9 in doing that pre-registrant investigation.

10 Q. And then it goes on to say, "In
11 order to determine whether a registrant has
12 provided effective controls against diversion,
13 the administrator shall use the security
14 requirements set forth in Sections
15 1301.72-1301.76 as the standards for the
16 physical security controls and operating
17 procedures necessary to prevent diversion."

18 So those are the key security
19 regulations that every proposed registrant must
20 be able to comply with, correct?

21 A. Yes.

22 Q. It then goes on to say that there's
23 a number of factors that have to be taken into
24 consideration regarding whether a registrant is
25 meeting or can meet the security requirements,

1 correct?

2 A. Yes.

3 Q. And it also says that strict
4 compliance is not required but rather
5 substantial compliance is what is required with
6 these security regulations, correct?

7 A. That's what it says.

8 Q. And that's what you look for,
9 correct, you look for substantial compliance
10 with these regulations when you do an
11 inspection, correct?

12 MS. CARROLL: Objection. Form.
13 The witness may answer.

14 A. That is what we consider when we do
15 our inspection.

16 Q. The first factor -- we're not going
17 to go through all these, thankfully, but the
18 first one is the type of activity conducted in
19 processing of bulk chemicals, preparing dosage
20 forms, packaging, labeling, cooperative buying,
21 et cetera. Would this also take into
22 consideration whether you're a self-distributor
23 like Giant Eagle, where you only distribute to
24 your own stores, or whether you distribute to
25 third-party strangers as well?

1 MS. CARROLL: Objection. Form.

2 The witness may answer.

3 A. I don't know if that addresses
4 specifically what you asked. I look at that
5 and it seems to be the type of activity,
6 whether it's a distributor, manufacturer,
7 repackager, relabeler.

8 Q. Well, let me ask you this: Do you
9 take that into consideration when you inspect a
10 distributor, whether they're a self-distributor,
11 like Giant Eagle, or whether they are a
12 distributor, like McKesson, where they
13 distribute to a third party?

14 A. In my experience, that is something
15 that I consider, yes.

16 Q. And would you agree that there is --
17 you know, just as a general matter, there would
18 be less risk of diversion if a distributor is
19 only distributing to its own stores as opposed
20 to a situation where they're distributing to
21 anybody who places an order with them?

22 A. I can't answer that, whether it's
23 less -- less potential for diversion, but that
24 is something that -- that I do personally on an
25 inspection. That is what I do consider.

1 Q. Let me ask you this then: Why do
2 you consider it? What is the relevance of that
3 fact?

4 MS. CARROLL: Objection. Form.
5 The witness may answer.

6 A. And, again, this is based upon my
7 experience, but we look at as far as a
8 distributor goes, they are to know who their
9 customers are and, as best as they can, the
10 customer of their customers, so that would be
11 something that I would consider.

12 Q. Right. And would you agree that if
13 you're only distributing to your own pharmacies,
14 then you obviously know your customers very well
15 because they're your own customers, correct?

16 A. That would depend upon what -- what
17 that applicant has in place. I don't know
18 necessarily how well they know their -- their
19 customer.

20 Q. Well, they would have hired the
21 pharmacist, who is placing the order, correct?

22 A. I'm not sure that I could speak to
23 who actually hired that -- that pharmacist.

24 Q. Well, not who individually -- let's
25 talk about Giant Eagle. Not who individually at

1 year the current one I'm working with would be,
2 so I can't answer that.

3 Q. Would you go to page 13 at the top
4 of this manual? You see the heading here is
5 Cyclic Investigations of Nonpractitioner CSA
6 Registrants? Do you see that?

7 A. Yes.

8 Q. A nonpractitioner would include a
9 distributor of controlled substances?

10 A. That's my understanding.

11 Q. And then if you skip down, there's a
12 paragraph beginning, "Full in-depth
13 investigations shall be conducted at least once
14 every three years for nonpractitioners."

15 Is that your understanding, that
16 every -- at least every three years you try to
17 perform a cyclic investigation on all
18 distributors in your area?

19 MS. CARROLL: Objection. Form.

20 Witness may answer.

21 A. I don't know what the current
22 policy is. In my experience, this -- this rate
23 of inspection has changed over the course of
24 time, so I don't know what the current --
25 current schedule is, whether it's once every

1 three years or longer.

2 Q. Well, generally, how often did you
3 do cyclic investigations of distributors since
4 you've been with the DEA? How often do you
5 generally try to do that; once every five years,
6 once every two years, you know, once every
7 three, whatever it might be?

8 A. I can't recall specifically. I
9 know it's -- from my memory, it would be once
10 every -- once every few years. So I can't
11 recall specifically that. It may depend upon,
12 you know, certain factors. So I don't know
13 what -- I don't know exactly.

14 Q. It says, "Emphasis shall be given to
15 inventory/recordkeeping, follow-up verification
16 of customers and orders, security, intelligence
17 collection and case support."

18 Does security include the SOM
19 system that the distributor has? Is that
20 something that you look at when you do a cyclic
21 investigation?

22 A. I believe that that SOM that you
23 referred to is in the security part of the
24 investigation.

25 Q. So that is something that you

1 yourself, when you do a cyclic inspection, look
2 at?

3 A. Yes.

4 Q. Could you go to page 130? Do you
5 see this is the section of the manual that
6 applies to pre-registration investigations?

7 A. I see that.

8 Q. And in the middle of that first
9 introductory paragraph it says, "The purpose of
10 the pre-registration investigation is to
11 determine the fitness and suitability of
12 registration investigation" -- I'm sorry, "of
13 the applicant to engage in the activities for
14 which registration is requested."

15 Would you agree with that statement
16 of purpose? Is that your understanding as well
17 for pre-registration inspections?

18 MS. CARROLL: Objection. Form.

19 The witness may answer.

20 A. That's what it states in the
21 manual.

22 Q. And that's your understanding as
23 well?

24 MS. CARROLL: Objection. Form.

25 Witness may answer.

1 A. That's my understanding, yes.

2 Q. At the bottom of that page under the
3 heading Pre-Registration Investigations, it
4 says, "An on-site investigation is required for
5 each applicant."

6 Do you see that statement?

7 A. Yes.

8 Q. Is that true that, in fact, whenever
9 you do a pre-registration inspection, it always
10 includes -- at least a portion of it is on-site?

11 A. For a distributor pre-registration
12 investigation, it would be in my experience.

13 Q. And do you try to be -- when you go
14 on-site and you do your inspection, do you try
15 to be as thorough as possible when you do that
16 inspection?

17 A. Personally, I make sure that I'm
18 thorough, yes.

19 Q. If you go to the next page, page
20 131, paragraph number 1, it indicates, "All
21 pre-registration investigative reports will
22 include information concerning the specific
23 controlled substances to be handled," and, you
24 know, it goes on to list a number of things.
25 And then it says, "The investigative report

1 should include a description of the security
2 maintained by the applicant, a description of
3 the recordkeeping and any other special
4 requirements planned by the applicant, and a
5 summary of an interview conducted with the
6 researcher's supervisor, verifying the
7 researcher's approval to conduct research."
8 Again, the security -- the reference to a
9 description of the security to be maintained,
10 does that include the suspicious order
11 monitoring system that the registrant plans to
12 use?

13 A. This particular site here, it looks
14 like it's just addressing researchers to me.

15 Q. As opposed to a distributor?

16 A. Yes.

17 Q. Well, let me just ask you this:
18 When you do a pre-registration inspection, you
19 do always look at the distributor's proposed SOM
20 system to make sure that it complies or will
21 comply with the SOM regulation?

22 A. We would look at the -- I would
23 want to know if they have a -- if they have a
24 system that they're going to be using to detect
25 suspicious orders.

1 circumstances."

2 Have you ever been involved in any
3 situation like that, where there's a
4 revocation, denial or surrender of registration
5 and, as a result, you've done an investigation,
6 a further investigation?

7 MS. CARROLL: Objection. Form.

8 Witness may answer.

9 A. Again, this would be what --
10 similar to what I answered just a moment ago,
11 was that I may have been party to such an
12 investigation, but I don't recall being the
13 primary investigator on -- specifically with
14 regard to a distributor, revocation, denial or
15 surrender for controlled substances.

16 Q. Number 4, it says, "Failure to
17 maintain adequate controls against theft and
18 diversion." And is it your understanding that
19 can be one of the reasons for the DEA seeking to
20 revoke, deny or cause the surrender of a
21 registrant's license?

22 A. My understanding is that is
23 something that we would consider, yes.

24 Q. If you do uncover any shortcomings
25 in a security system used by a distributor when

1 you're inspecting them, do you have a discussion
2 with management about that? Is that something
3 that you would discuss with them?

4 MS. CARROLL: Objection. Form.
5 Witness may answer.

6 A. Whether it's a pre-registrant or a
7 scheduled investigation, that is something that
8 we would -- that I would want to discuss with
9 management.

10 Q. Would you go to page 162 of Exhibit
11 6? There's a heading there, Discussion with
12 Management. "At the discretion of the group
13 supervisor, the investigators should discuss
14 their findings with him/her prior to discussing
15 the alleged violations with the firm's
16 management. Significant recordkeeping
17 discrepancies should be supported with
18 documentation."

19 And then number 2, it says, "The
20 firm should be informed of what courses of
21 action against it are possible but not the
22 specific action the investigators intend to
23 recommend."

24 Do you see that?

25 A. Yes.

1 when they opened for business?

2 MS. CARROLL: Objection. Form.

3 Witness may answer.

4 A. Ask the question again. I'm sorry.

5 Q. Yes. So one of the things that you
6 were looking closely at was whether Giant Eagle
7 was going to be able to comply with the SOM
8 regulation when it opened for business?

9 A. Well, since they had not handled
10 controlled substances at that point, I don't
11 know that they were able to comply, but I was
12 notifying them of the specific CFR requirement
13 to design and operate the suspicious order
14 system.

15 Q. If you go to the next page, at the
16 very top, page 3, it says, "DI Colosimo reviewed
17 each of these items with Carlson, Zelaski,
18 Fleming, and Beiter" from Giant Eagle. So you,
19 in fact, had a discussion with them about, among
20 other things, the SOM regulation, correct?

21 A. Yes.

22 Q. And then if you go down to the
23 middle of the page, there's a paragraph that
24 says, "According to Carlson, HBC will store all
25 original purchase and sales information at their

1 have to report your findings to your group
2 supervisor, correct?

3 A. Yes.

4 Q. And he or she is going to rely on
5 the findings that you provide him or her,
6 correct?

7 A. That's my understanding.

8 Q. And, in addition, you're going to
9 report those findings to the registrant
10 applicant, correct?

11 A. What do you mean by that?

12 Q. Again, if you thought that there was
13 an issue or there was a problem with compliance,
14 you would want to let the registrant know so
15 that hopefully they can correct the problem,
16 correct?

17 A. Yes, that would be part of it.

18 Q. So -- and wouldn't it be -- wouldn't
19 you agree that it would be reasonable for the --
20 if you do your investigation and you have a
21 meeting with management and you say from
22 everything I've seen, you meet all of the
23 requirements, you're good to go, they should be
24 able to rely on what you're telling them, right,
25 that their systems, their security systems that

1 they have in place are at least adequate, if not
2 more than adequate, under the DEA regulations?

3 MS. CARROLL: Objection. Form.

4 The witness may answer.

5 A. I mean, insofar as what I'm able to
6 determine on that pre-registrant investigation,
7 I would agree with that.

8 - - - - -

9 (Thereupon, Defendants' Deposition
10 Exhibit 20, Report of Investigation
11 dated January 11, 2016, Beginning
12 Bates Stamp DEA-T1BCC-00001846, was
13 marked for purposes of
14 identification.)

15 - - - - -

16 Q. Would you turn to Exhibit 20, page
17 1? You see this is another report of
18 investigation by yourself, and it says, "Other
19 officers: Kurt Dittmer, RPS Patricia Robison,"
20 and "Kayla" -- I'm probably going to butcher the
21 name -- "Solonichne." Can you tell us what this
22 investigation -- which investigation this was
23 that you were involved in?

24 A. This was a pre-registrant
25 investigation of the Giant Eagle Rx

1 Distribution Center that proposed -- that
2 applied to open a distributor of Schedules 2
3 through 5 controlled substances in Freedom,
4 Pennsylvania.

5 Q. Was it your understanding that this
6 was a -- going to be a new warehouse for Giant
7 Eagle that was going to also distribute Schedule
8 2 controlled substances to Giant Eagle's own
9 pharmacies?

10 A. Yes, Schedules 2 through 5.

11 Q. Were you involved in any cyclic
12 investigations that the DEA performed on HBC
13 between 2009, when you did the pre-registrant
14 inspection, and the time of this investigation
15 of the proposed GERx facility in 2015?

16 A. I don't recall being involved with
17 any of those scheduled or cyclic
18 investigations.

19 Q. When you do a -- an investigation
20 like -- where there's a pre-registrant
21 investigation or a cyclic investigation, do you
22 talk to any of your colleagues who may have been
23 involved in other earlier investigations of the
24 registrant?

25 A. Sometimes I do that.

1 Q. And don't you usually try to note in
2 your report what the outcome of prior
3 investigations of that registrant have been, you
4 know, whether they passed or whether they had
5 issues or anything like that?

6 MS. CARROLL: Objection. Form.
7 The witness may answer.

8 A. We would include -- I would
9 personally include the results of any prior
10 inspections that took place.

11 MR. LIVINGSTON: I'd like to just
12 take a short restroom break, if that's okay
13 with everyone.

14 THE WITNESS: That's fine with me.

15 THE VIDEOGRAPHER: We're off the
16 record.

17 (Recess had.)

18 THE VIDEOGRAPHER: We're on the
19 record.

20 BY MR. LIVINGSTON:

21 Q. Mr. Colosimo, from time to time did
22 Giant Eagle ever ask you for any advice
23 regarding any of the security requirements
24 relating to controlled substances?

25 A. I believe after the -- after the

1 second Giant Eagle Rx Distribution Center
2 application was approved, I believe I did
3 contact them with -- or they -- one of the
4 Giant Eagle representatives contacted me
5 regarding some physical security aspect. I
6 can't recall specifically what that was, but I
7 think there was discussion about a physical
8 security issue.

9 Q. Okay. And did you provide any
10 guidance?

11 A. I can't recall specifically. Yeah,
12 I don't recall specifically, but I do remember
13 the request, but I can't remember what the
14 request was about.

15 Q. Okay. Well, let's turn back to
16 Exhibit 20, page 1, which was your investigation
17 report for the GERx facility before it opened.

18 Under the heading Subject Firm's
19 Background, you refer to the fact that HBC
20 currently -- you know, that currently, since
21 October of 2009, Giant Eagle's HBC facility was
22 a distributor of Schedule 3 through 5.

23 Do you see that?

24 A. Yes.

25 Q. And then below that you indicate

1 that "HBC has been the subject of three in-depth
2 cyclic investigations by the Pittsburgh D.O.,"
3 and then there's some redactions, but it says,
4 "None of which resulted in any administrative
5 actions."

6 So did you look back on those prior
7 in-depth cyclic investigations to see what the
8 outcome of those investigations was?

9 A. Yes.

10 Q. Do you remember which years those
11 cyclic investigations took place?

12 A. I believe the first one would have
13 been within a few years of the -- of their
14 approval. The others, I can't recall
15 specifically when those would have been.

16 Q. And did you just look at written
17 records of those prior investigations or did you
18 talk to the DEA folks who were involved in those
19 investigations or both?

20 A. I would have reviewed the written
21 file. I can't recall if I spoke with -- with
22 the investigators. I can't recall
23 specifically.

24 Q. Would you go to the next page? At
25 the very top it's talking about HBC. It says,

1 "The subject firm was the subject of in-depth
2 chemical regulatory cyclic investigations in
3 2002, 2004, 2008 and 2014. No violations were
4 uncovered during these investigations."

5 Now, you're referring here to the
6 List 1 chemical inspections; is that correct?

7 A. Yes.

8 Q. And, again, I mean, so -- when you
9 went out to the GERx facility to inspect it
10 before it opened, at that time you knew that
11 Giant Eagle's HBC facility had not had any
12 issues with respect to compliance with DEA
13 regulations during any of these audits going
14 back all the way to 2002, correct?

15 A. Could you ask that question again?

16 Q. Yes.

17 I mean, your report refers to every
18 single DEA inspection of HBC's facility, some
19 of which go back to 2002. You knew at the time
20 you went out to the GERx facility to check that
21 facility out before it opened that Giant
22 Eagle's HBC facility had essentially passed
23 every single inspection that the DEA had
24 conducted going all the way back to 2002?

25 MS. CARROLL: Objection. Form.

1 Mischaracterizes his statement.

2 Witness may answer.

3 A. I believe on page 1 of that report
4 I indicated that the three inspections of the
5 HBC facility did not result in any
6 administrative action, such as a letter of
7 admonition.

8 Q. Well, again, not to quibble, but you
9 reviewed those reports and one of those reports
10 was -- or a couple of those reports were
11 actually ones you authored, and all of those
12 reports indicated that there were no violations
13 discovered during those inspections going all
14 the way back to 2002, correct?

15 MS. CARROLL: Objection. Form.

16 The witness may answer.

17 A. You're distinguishing between the
18 controlled substance investigations that's
19 scheduled in the List 1 chemicals --

20 Q. I'm including both.

21 A. -- and as I indicated earlier, the
22 investigation of the controlled substance
23 facility, HBC, did not result in any
24 administrative action. I did not say that
25 there was not -- there were not issues that --

1 says, "As noted above, prior cyclic
2 investigations conducted at HBC have not
3 resulted in any administrative actions. HBC was
4 the subject of its first regulatory
5 inspection/cyclic investigation in May 2011, and
6 documented under DEA file number," which is left
7 blank. "The result of this investigation
8 revealed minor recordkeeping violations (an
9 overage due to computer software malfunction)."
10 And "This issue was resolved on-site."

11 Do you see that?

12 A. Yes.

13 Q. The reference to "This issue was
14 resolved on-site," meaning that there was -- it
15 was not considered to be a real violation, that
16 it was just a software malfunction and it was
17 resolved at the time?

18 MS. CARROLL: Objection. Form.

19 Witness may answer.

20 A. That did not result in a formal
21 administrative action. That issue was resolved
22 on-site and I included that in my report.

23 Q. And you reviewed this May -- did you
24 review this May 2011 investigation report?

25 A. Yes.

1 my experience, I recommend more frequent, more
2 routine physical counting to eliminate or to
3 mitigate against diversion.

4 Q. Would you go to page 10 of your
5 report under the heading Due Diligence? It
6 says, "Because the supplier (GERxDC) and
7 customers (Giant Eagle pharmacies) are owned by
8 Giant Eagle Inc., GERxDC will have access to
9 customer information that will assist them in
10 enacting the following 'due diligence' actions."

11 Again, so it was your understanding
12 that Giant Eagle, because it was only
13 distributing to its own customers, would have
14 very in-depth information relating to its
15 customers?

16 A. Well, that they would have -- that
17 they would have dispensing ordering information
18 for their -- for their customers, prescription
19 information.

20 Q. Well, let's just take some for
21 examples. They would know if, for example, a
22 competitor pharmacy across the street either
23 just opened or just closed, right, which might
24 affect how much prescriptions they would end up
25 needing to fill?

1 MS. CARROLL: Objection. Form.

2 Witness may answer.

3 A. I don't know. You would have -- I
4 would have to ask that pharmacy, that, you
5 know, representative in their headquarters if
6 they knew about that specifically. I don't
7 know. I'd be speculating as to what they would
8 know.

9 Q. But you do think it's important to
10 note this information in your reports, correct?

11 A. Which information is that?

12 Q. The fact that Giant Eagle's only
13 customers for its GERx facility were its
14 pharmacies.

15 A. Yes. It's important to put in
16 there.

17 Q. If you go down to under Customer
18 Authentication, the paragraph in the middle, it
19 says, "The GERxDC only services Giant Eagle
20 pharmacies which are owned by Giant Eagle, Inc.
21 If, for any reason, a Giant Eagle pharmacy is
22 not licensed to receive Legend drug products or
23 controlled substances, the GERxDC will no longer
24 service the pharmacy."

25 Now, you understood from this that

1 Giant Eagle, again, was going to be monitoring
2 its own pharmacies to make sure that they were
3 at all times -- that they at all times had a
4 current DEA license, and if for some reason
5 they didn't, GERx would immediately stop
6 shipping controlled substances to that
7 pharmacy, correct?

8 A. That's what I stated in my report.
9 That's my understanding.

10 Q. Then on the next page, 11, there's a
11 section called -- a whole section on Suspicious
12 Orders, correct?

13 A. Yes.

14 Q. Okay. And we're not going -- for
15 time reasons, we're not going to go through this
16 whole thing -- it goes on for a few pages -- but
17 you ultimately concluded that the proposed
18 suspicious order system was -- that it would be
19 compliant with DEA regulations?

20 A. In my report I described the system
21 as represented to me by Giant Eagle. I did not
22 evaluate its effectiveness. I just -- I
23 completely described it as they represented to
24 me in -- with the handout that they gave me.

25 Q. I'm just -- I mean, at the end --

1 sense.

2 MR. MOUGEY: Objection.

3 Q. I mean, if I'm wrong about that,
4 please let me know.

5 MS. CARROLL: Objection.

6 Witness may answer.

7 A. There was a series of questions
8 that you asked there.

9 Q. I was trying to just explain the one
10 question that I asked, but maybe I'll try it
11 again. Isn't it true that if an applicant has a
12 SOM system that the DEA knows does not comply
13 with the regulations, that either they're going
14 to require the applicant to comply, or if the
15 applicant is adamant and won't comply, the DEA
16 will take some sort of administrative or other
17 action against the applicant or registrant?

18 MS. CARROLL: Objection to form.

19 The witness may answer.

20 A. In my experience, I would take
21 administrative action and ensure that there was
22 compliance. That would be corrected on-site.

23 Q. So can't we rest assured that at the
24 time you went out to GERxDC in 2015, that HBC's
25 SOM system was viewed by the DEA at that time as

1 The witness can answer.

2 A. My understanding is that there was
3 oversight of the warehouse by -- at the
4 corporate level by Giant Eagle.

5 - - - - -

6 (Thereupon, Defendants' Deposition
7 Exhibit 3, Reports of Investigation
8 Beginning Bates Stamp
9 US-DEA-00033016, was marked for
10 purposes of identification.)

11 - - - - -

12 Q. Would you turn to Exhibit 3, page 9?
13 Do you see that this is a report of
14 investigation by Michael Kupchick from your
15 office and it was prepared on May 20, 2011? Is
16 this one of the investigation reports of HBC's
17 facility that you reviewed?

18 A. Yes.

19 Q. And it says -- this was a cyclic
20 investigation, correct?

21 A. Yes.

22 Q. And it says that Mr. Kupchick had
23 some assistance from Vincent Tomei from your
24 office as well?

25 A. Yes.

1 Q. You would agree that both of those
2 individuals are very competent and highly
3 dedicated DEA inspectors, correct?

4 A. I work with both Investigator
5 Kupchick and Investigator Tomei.

6 Q. And they're both competent and
7 conscientious, correct?

8 MS. CARROLL: Objection to form.
9 The witness may answer.

10 A. I'm not the supervisor of either of
11 those investigators.

12 Q. Well, do you trust their work? I
13 mean, do you trust their work?

14 A. What do you mean by that?

15 Q. Well, you reviewed this work product
16 that they produced, this report, and you seem to
17 rely on it at least to some extent. Did you
18 trust the accuracy of the report when you
19 reviewed it?

20 A. The accuracy of the report?

21 Q. Yes.

22 A. I don't recall that there was
23 anything in there that I disagreed with that
24 was not accurate.

25 Q. A little further down it says, "This

1 investigation revealed no discrepancies with
2 respect to security." The security regulations
3 include the SOM regulation, correct?

4 MS. CARROLL: Objection.

5 A. This is not my report. This is
6 Investigator Kupchick's report.

7 Q. Right, I know, but you read the
8 report. And what did you understand this
9 reference to be referring -- to mean, "This
10 investigation revealed no discrepancies with
11 respect to security"?

12 A. After reading the report, and this
13 is my perspective, no discrepancies with regard
14 to physical security at the facility, at the
15 warehouse.

16 Q. Was it your understanding that at
17 this time HBC was still using the Vocollect scan
18 system for inventory control?

19 A. I don't know if that was mentioned
20 in this report.

21 Q. Why don't you go to page 19. At the
22 top it says, "All selections are performed using
23 Vocollect directed activity." Does that refresh
24 your recollection that in 2011 HBC was still
25 using the Vocollect system?

1 A. Yes.

2 Q. What does the report mean when it
3 says "no discrepancies"? Is that the same as no
4 violations? What does that mean?

5 MS. CARROLL: Objection. Form.
6 Witness may answer.

7 A. I don't -- I'm not sure of the
8 distinction. In my opinion, the violation
9 would be something that would rise to the
10 issuance of a formal administrative letter or
11 administrative action. The discrepancy could
12 be -- and, again, this is my perspective,
13 discrepancy could be some issue that was
14 resolved on-site where it did not rise to the
15 level of an administrative action.

16 Q. In your mind, the violation is more
17 serious than just a discrepancy, which is a very
18 minor issue, correct?

19 MS. CARROLL: Objection. Form.
20 The witness may answer.

21 A. They would be both issues that need
22 to be resolved in my perspective.

23 Q. Could you go to page 40, please?
24 This is a report of investigation by John Conlon
25 from your office prepared August 13, 2013

1 relating to the HBC facility. Did you review
2 this report?

3 A. Yes.

4 Q. And then at the very bottom of the
5 synopsis on the first page, it says, "This
6 investigation revealed no discrepancies with
7 respect to recordkeeping or security."

8 Do you see that?

9 A. Yes.

10 Q. So this -- again, we have another
11 indication here that HBC essentially has a clean
12 inspection report, correct?

13 MS. CARROLL: Objection. Form.
14 The witness may answer.

15 A. That's what Investigator Conlon
16 indicated, no discrepancies with respect to
17 recordkeeping or security.

18 Q. And this report would have also, as
19 part of this -- of the inspection, would have
20 looked at HBC's SOM system at the time, correct?

21 A. I believe this did.

22 Q. Would you go to page 42? The
23 heading is "Subject Firm's Background. At the
24 very bottom of that first paragraph it says,
25 "HBC Service Company had 157 million dollars in

1 Q. Okay. So is it your understanding
2 that essentially the DEA is saying, hey, you
3 know, you've been in compliance with the reg but
4 we think you can improve it possibly by going to
5 an automated system, right? Was that your
6 understanding of what was being suggested to
7 Giant Eagle at this time?

8 MS. CARROLL: Objection. Form.
9 The witness may answer.

10 MR. MOUGEY: Objection.

11 A. That's -- my understanding is that
12 the DI Investigator Conlon made suggestions,
13 noted that there was no computerized system to
14 detect that and made a suggestion to Mr. Rogos
15 to have that implemented.

16 Q. If you go to the next page, 53,
17 under Meeting with Management, it says, "During
18 this meeting, investigators advised Rogos that
19 both recordkeeping and security are in full
20 compliance with the requirement set forth in
21 Title 21 Code of Federal Regulations."

22 That includes the SOM regulation,
23 correct?

24 MS. CARROLL: Objection. Form.
25 Witness may answer.

1 A. The SOM regulation, I mean, insofar
2 as that is under security, that's accurate.

3 Q. So he says that, Giant Eagle, you're
4 in full compliance, tells Giant Eagle you're in
5 full compliance with all the security regs,
6 including the SOM regs, but then he says, but,
7 you know, I advised Mr. Rogos to develop a
8 better system of due diligence, correct? So
9 he's saying we think you can improve your
10 system, here's our advice, and then Mr. Rogos
11 said he would follow up, correct?

12 MS. CARROLL: Objection. Form.
13 The witness may answer.

14 A. Those are your words. I'll read
15 it. "Investigator Conlon advised Rogos to
16 develop a better system of due diligence,"
17 period.

18 Q. Right after he told Mr. Rogos, and I
19 assume he was being a hundred percent honest,
20 that Giant Eagle, with all of the security
21 requirements, which, of course, includes the SOM
22 requirement, correct?

23 MS. CARROLL: Objection. Form.
24 The witness may answer.

25 A. And, again, my understanding is

1 that the suspicious orders would fall under
2 security.

3 Q. Let's take a look at to see if Giant
4 Eagle tried to follow up with what Mr. Conlon
5 had recommended.

6 - - - - -

7 (Thereupon, Defendants' Deposition
8 Exhibit 16, E-Mail String Beginning
9 Bates Stamp HBC_MDL00136952, was
10 marked for purposes of
11 identification.)

12 - - - - -

13 Q. Would you go to Exhibit 16? Just
14 for reference, we were just looking at the
15 report from August of 2013. You see Exhibit 16
16 is an e-mail from Joseph Millward at Giant Eagle
17 to some other folks at Giant Eagle dated
18 November 14, 2013 regarding daily HBC suspicious
19 purchasing report.

20 Do you see that?

21 A. Yes.

22 Q. If you skip down to the bottom, this
23 is an e-mail response to another e-mail from
24 Kayla Voelker at Giant Eagle, and she says, "We
25 had two pharmacies exceed the purchasing

1 thresholds of certain controlled products so far
2 this month." So do you see that Giant Eagle a
3 few months later already had the automated
4 threshold system in place for suspicious order
5 monitoring?

6 MS. CARROLL: Objection. Form.
7 The witness may answer.

8 A. I don't know what they had in
9 place. This is an e-mail that you're referring
10 to that addresses thresholds.

11 Q. Right. Which is what an automated
12 threshold system does, right? It has --
13 automatically when you hit a certain threshold
14 at a store for purchasing a certain item, it's
15 flagged, right?

16 MS. CARROLL: Objection. Form.
17 The witness may answer.

18 A. I'm familiar with the term
19 "threshold," but I don't know what Giant Eagle
20 had in place at this time to detect that.

21 Q. Hasn't Giant Eagle -- didn't Giant
22 Eagle report some suspicious orders to you
23 telephonically or by e-mail?

24 MS. CARROLL: Objection. Form.
25 Vague.

1 A. I reviewed this report among others
2 before it was approved.

3 Q. And the report concludes that --
4 says, "This investigation revealed no
5 discrepancies with respect to recordkeeping or
6 security," correct?

7 A. Yes.

8 Q. And that would have included no
9 discrepancies with respect to Giant Eagle's SOM
10 system at its GERx facility?

11 MS. CARROLL: Objection. Form.
12 The witness may answer.

13 A. Again, the SOM system would be
14 under -- my understanding, it would be under
15 the security portion.

16 MR. LIVINGSTON: I'll pass the
17 witness and reserve any time I may still have
18 left.

19 MS. CARROLL: Is this a good time
20 to take a short break?

21 MR. LIVINGSTON: Sure.

22 THE VIDEOGRAPHER: We're off the
23 record.

24 (Recess had.)

25 THE VIDEOGRAPHER: We're on the

1 and security are in full compliance with the
2 requirements in Title 21 CFR"? That tells you,
3 sir, that Giant Eagle was told at this time that
4 it was meeting all of the security requirements,
5 including the SOM regulation, correct?

6 MS. CARROLL: Object to the form.

7 The witness may answer.

8 A. Yeah. According to that sentence,
9 it does indicate that Investigators Conlon and
10 Sousa advised Rogos and Kuchta that
11 recordkeeping and security are in full
12 compliance. That's what it says.

13 Q. Okay. And, sir, if you go back to
14 the previous page -- I guess it's actually page
15 69 of this exhibit -- this is that discussion
16 that -- between Mr. Rogos and the DEA
17 investigators about Giant Eagle's SOM system at
18 the time, correct? You were just asked some
19 questions about this from Mr. Mougey.

20 A. Yes.

21 MS. CARROLL: Objection. Form.

22 The witness may answer.

23 Q. Sir, isn't this literally word for
24 word identical to what was in the previous
25 report from August of 2013 that we looked at